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10/681,745	10/08/2003	Suzie Hwang Pun	ITI-P01-010	8153

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BETTON, TIMOTHY E	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	**Application No.** 10/681,745	**Applicant(s)** PUN ET AL.	
	Examiner Timothy E. Betton	**Art Unit** 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *6,8, and 18 -30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,9-17, and 31-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' Remarks filed 2 October 2007 have been acknowledged and duly made of record.

The essence of applicants' argument is drawn to the statement as follows: They [the references used in the 103(a) rejection] do not teach linking molecules with the structural features and properties recited in the instant claims 1 and 15-17.

Further, applicants' purport The Kosak et al. reference is deficient in paragraphs [0082] and [0091] due to disclosure of "covalent cross-link bonds" and "a biocleavable cross-linking agent."

In view of the above, applicants' arguments are considered; however, they are not found to be persuasive.

In response, the instant specification is absent of any such disclosure directed to unexpected results due to the alleged distinct structural features and properties. It would be instantly apparent to the skilled artisan that cyclodextrin moieties and linking molecules crosslink the polymer through such inclusion complexes. The occasion of at least two, three, four, etc. moieties that form inclusion complexes with the inclusion hosts appear to be inconsequential to claimed objective of instant invention. The skilled artisan would be inclined to recognize with any reasonable expectation that the claim of "at least two moieties" is adequately overcome by the well-established teachings that under certain conditions by which the complex forms, reasonably "at least two moieties" may exist and reasonably more than two moieties.

Also, the disclosure of Kosak et al in paragraphs [0082] and [0091] adequately address and the limitations in applicants' specification (pg 33) and instant claims. The instant specification cites:

The **covalent linkage between the moieties may be any suitable linkage**, such as an alkylene chain, a polyethylene glycol (PEG) chain, poly (ethyleneimine), an oligosaccharide, an amino acid chain, or any other suitable linkage. The linkage can be stable under physiological conditions, such as an alkylene chain, or it can be cleavable under physiological conditions, such as by an enzyme (e.g., the linkage contains a peptide sequence that is a substrate for a peptidase), or by hydrolysis (e.g., the linkage contains a hydrolyzable group, such as an ester or thioester). The linkage can be biologically inactive, such as a PEG, polyglycolic acid, or polylactic acid chain, or can be **biologically active**, such as an oligo- or polypeptide that, when **cleaved** from the moieties, binds a receptor, deactivates an enzyme, etc. **Various oligomeric linkages that are biologically compatible and/or bioerodible are known in the art** and the selection of the linkage may influence the ultimate properties of the material, such as whether it is durable when implanted, whether it gradually deforms or shrinks after implantation, or whether it gradually degrades and is absorbed by the body. The linkage may be attached to the moieties by any suitable bond or functional group, including carbon-carbon bonds, esters, ethers, amides, amines, carbonates, carbamates, sulfonamides, etc.

Paragraph 82 and 91 of Kosak et al. are replete with representative examples and/or embodiments of linking molecules cross linking the polymer through inclusion complexes.

Thus, the skilled artisan would instantly recognize that based on the properties and characteristics of polymeric complexes that several moieties may participate in the linkage. Based on the nature of the art, the occurrence of the linking of moieties (of at least two) would not be unexpected or uncommon.

Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 9, 10-17, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Middleton et al. Synthetic biodegradable polymers as orthopedic devices, Biomaterials 21 (2000) pgs 2335-2346, and Kosak (USPGPUB 20011003433 A1) in view of Rohrbach et al (USPN 5098793).

For the reasons already made of record, the rejection of Middleton et al. and Kosak et al. are maintained from the previous office action.

Accordingly, Rohrbach et al. teach a large class of crosslinked cyclodextrin resins soluble in water to an extent under about 200 ppm but soluble in an organic solvent to an extent of at least 0.1 weight percent have good film-forming properties with a wide variety of solid phase substrates. The films exhibit excellent adhesive properties toward virtually all solid surfaces which consequently can be readily coated with a thin film having a multiplicity of cyclodextrin moieties available at the surface for separation and/or purification. Such coated substrates can be prepared in a variety of sizes, shapes, and cyclodextrin loading quite conveniently and relatively inexpensively (abstract only).

Rohrbach et al. teach the versatility of cyclodextrin moieties. Cyclodextrins are cyclic molecules consisting of 1-4 linked alpha-D-glucopyranose monomeric units. The cyclodextrins containing 6-, 7-, and 8-glucose units joined to form a ring, commonly known as alpha-, beta-, and gamma-cyclodextrin respectively, are the most important cyclodextrins to date, possibly because of their availability relative to cyclodextrins of different ring size. The usefulness of these cyclodextrins arises from their ability to reversibly form inclusion complexes, or clathrates, with many types of compounds. Inclusion complexes arise when a host molecule, such as a cyclodextrin has a structure containing an interior cavity into which guest molecules can bind by weak interactions such as van der Waal's forces. The latter are short range forces which are sufficiently strong to allow the formation of definite, generally solid complexes, but are sufficiently weak to permit ready dissociation of the complex to a host and guest molecule (column 1, lines 12-29).

Further, Rohrbach et al. teach the cyclodextrin [including] guest molecules that the skilled artisan would instantly recognize as obvious over instant claims 2-5 (column 5, lines 53-63; column 6, lines 14-63).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ardin H Marschel 12/17/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER

TEB